

**510(k) Summary
For
miniMaster LED Ultrasonic Scaler**

1. SPONSOR

E.M.S. Electro Medical Systems SA
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CH - 1260 Nyon
Switzerland

SEP 08 2010

Contact Person: Suzanne Fassio-Hardy
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Date Prepared September 3, 2010

2. DEVICE NAME

Proprietary Name: miniMaster LED
Common/Usual Name: Ultrasonic Scaler
Classification Name: Ultrasonic Scaler (21 CFR 872.4850, Product Code ELC)

3. PREDICATE DEVICES

- miniMaster Ultrasonic Scaler (K050710)
- Piezon Master 700 (K093000)

4. INTENDED USE

- Removing supra and subgingival calculus deposits and stains from the teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planning
- Releasing crowns, bridges, inlays and posts as well as condensing gutta percha
- Plugging for amalgam condensation
- Amalgam burnishing
- Preparing, cleaning, and irrigating root canals
- Preparing approximal cavities
- Cementing inlays and onlays
- Retrograde preparation of root canals

5. DEVICE DESCRIPTION

The miniMaster LED is an ultrasonic scaler consisting of a main chassis containing an external electric power supply, controls and displays, ultrasonic generator, and a bottle-fed irrigation system. A 2-step footswitch is connected to the main chassis by a footswitch cord. A handpiece is connected to the main chassis by a handpiece cord, with irrigant flow control located on the cord itself. Instruments designed for specific dental procedures are attached to the distal end of the handpiece.

The miniMaster LED is a modification of the miniMaster Ultrasonic Scaler that was the subject of K050710. The overall design of the miniMaster LED is identical to the design of the miniMaster. The introduction of Piezon handpiece LED, materials changes to the peristaltic pump tubing, and design modifications implemented for the miniMaster LED were made to improve the functional performance and ease of use of the ultrasonic scaler. These design changes are listed in Table 1.

Table 1. Design Modifications Incorporated in the miniMaster LED

Ultrasonic Scaler Component/Accessory (Part Reference)	Design Modification
Piezton handpiece LED (EN-060/A)	Compatibility with Piezon handpiece LED which includes a light guide and 6 LEDs placed under the nozzle to improve illumination of the treatment area.
Handpiece LED cord (EM-113A/A)	Handpiece cords adapted to integrate LEDs
Cord connector (EK-300)	Cord connectors adapted to support LED
Water adjustment ring	Water adjustment ring relocated to handpiece side of handpiece cord
Electronics	Electronic PCB upgraded to drive the LED
Peristaltic Pump tubing*	Internal irrigation tubing replaced with fluorocarbon rubber material

PCB = printed circuit board

LED = light emitting diode

* Peristaltic Pump identical to Piezon Master 700, K093000

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the proposed and predicate devices is provided in Table 2.

Table 2. Comparison of Technological Characteristics of Proposed and Predicate Devices

Item for Comparison	miniMaster	miniMaster LED
Intended Use	Ultrasonic scaler intended for use in dental and periodontal cleaning, preparatory, endo and restorative procedures.	
Operational environment	Stand alone	Stand alone
Power supply	<ul style="list-style-type: none"> • External transformer 24 V • 100-240V/50-60 Hz 	<ul style="list-style-type: none"> • External transformer 24 V • 100-240V/50-60 Hz
Water supply	<ul style="list-style-type: none"> • Irrigating liquid bottle • Peristaltic pump 	<ul style="list-style-type: none"> • Irrigating liquid bottle • Peristaltic pump
Ultrasonic power adjustment	Ten discrete power settings	Same
Water adjustment	<ul style="list-style-type: none"> • Flow regulator on handpiece cord • Flow rate: 0-50 ml/min. minimum 	<ul style="list-style-type: none"> • Flow regulator on handpiece cord • Flow rate: 0-50 ml/min. minimum
Dry/Wet work capability	<ul style="list-style-type: none"> • miniMaster: Both Wet and Dry Work • ULTRAPIEZON: Wet Work only 	<ul style="list-style-type: none"> • miniMaster: Both Wet and Dry Work
Output performance specifications	0-8 W Standard Mode 0-4.5 W Soft (Endo) Mode 24-32 kHz (nominal)	Same (Soft mode identified as "ENDO mode")
Footswitch	Electrical command, two positions for independent control of water flow and ultrasonic tip movement	Same
Materials:		
Handpiece	<ul style="list-style-type: none"> • Autoclavable plastic 	<ul style="list-style-type: none"> • Autoclavable plastic
Instruments	<ul style="list-style-type: none"> • Stainless steel 	<ul style="list-style-type: none"> • Stainless steel
Main Chassis Weight and Dimensions	Weight: 1.3 kg Height: 96 mm Width: 213 mm Length: 80 mm	Weight: 1.3 kg Height: 96 mm Width: 213 mm Length: 80 mm

7. NON-CLINICAL TESTING

The appropriate design verification and design validation activities were conducted to address the potential risks identified in the Hazard Analysis. Testing conducted on the proposed miniMaster LED included the following:

- UL 60601-1, "Medical Electrical Equipment—Part 1: General Requirements for Safety" (2nd edition including amendments 1&2)
- IEC 60601-1-2, "Medical electrical equipment. Part 1 General requirements for safety – Part 2 Collateral standard: Electromagnetic compatibility: Requirements and Tests" (1993)
- ISTA 2A, "Packaged-Products 150 lb (68 kg) or Less"

The reprocessing instructions for the reusable handpiece, instruments, and accessories were validated in accordance with ANSI/AAMI ST79:2006, "Comprehensive guide

to steam sterilization and sterility assurance in health care facilities". The steam sterilization process was validated to an SAL of 10^{-6} using a half cycle method in accordance with ANSI/AAMI/ISO 17665-1:2006 "Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices".

8. CLINICAL TESTING

No clinical testing was submitted to support the claim of substantial equivalence.

9. CONCLUSIONS

The proposed and predicate devices have the same general intended use and principles of operation. The overall design of the proposed and predicate devices is similar. The differences between these devices are limited to design modifications implemented to replace the ultrasonic module and improve the product's ease of use. These design modifications are minor and raise no new issues of safety or effectiveness.

The miniMaster LED met all defined acceptance criteria for the non-clinical testing listed in Section 7. The information provided confirms that the miniMaster LED is safe and effective for its intended use and performs as well or better than the miniMaster.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

EMS Electro Medical Systems SA
C/O Ms. Cynthia J.M. Nolte
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

SEP 08 2010

Re: K093723

Trade/Device Name: miniMaster LED
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: August 30, 2010
Received: August 31, 2010

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

lease be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K093723

Device Name: miniMaster LED

SEP 08 2010

Indications for Use:

The miniMaster LED is an ultrasonic scaler that is intended for the following:

- Removing supra and subgingival calculus deposits and stains from the teeth
- Periodontal pocket lavage with simultaneous ultrasonic tip movement
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- Releasing crowns, bridges, inlays and posts as well as condensing gutta percha
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- Preparing approximal cavities
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- Retrograde preparation of root canals

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K093723